1. Do any devices involved in this study meet FDA’s definition of [medical device](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm)?

*If no*, you do not need to complete and submit this form. However, any devices used in this study, even those which do not meet FDA’s definition of medical device, must be described in the protocol - including how they operate and how they will be utilized with subjects. *If yes*, continue to #2.

1. List each item meeting the definition of Medical Device from #1 above, and provide the requested information for each device (refer to the Instructions page for guidance).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Common and/or Proprietary Name of Medical Device?
 | 1. Manufacturer? (If you are building or developing the device, indicate here.)
 | 1. Will you be testing

***Safety or Effectiveness***? *Review Instructions to make determination.* (Yes/No) | 1. Current FDA Status? *Review Instructions for options.*
 | 1. Uploaded device manual, instructions, photos, spec sheets, or other relevant safety/device information for the IRB to consider during protocol review? (Yes/No; if no, indicate why not)
 |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

If you answered “yes” in ***column c*** above for any device (**hereafter referred to as Column C devices**), continue to #3. If you do not have any **Column C** devices, STOP HERE.

1. For any ***Column C*** devices:

	1. Does the device qualify as a “General Wellness Device – Low Risk” (Review [FDA Guidance](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf) for this determination)? If yes, please specify which device(s) from Column C above this applies to, and explain how it meets FDA’s criteria:
	2. Does the device qualify as “Non-Medical Exercise Equipment” (Review Instructions for guidance)? If yes, please specify which device(s) from Column C above this applies to, and explain how it meets the criteria:
	3. Does the device’s use in the study meet criteria for [IDE Exempt by FDA](https://www.ecfr.gov/current/title-21) (Review Instructions for guidance)? If yes, please specify which device(s) from Column C this applies to, and how it meets FDA’s exemption criteria:

If all **Column C** devices qualify under item 3 a, b, or c above, STOP HERE. If not, continue to #4, #5, and #6.

1. ***Column C*** devices that do not qualify as a General Wellness Device – Low Risk, Non-Medical Exercise Equipment, or IDE Exempt are considered a “Regulated Medical Device” and must undergo a risk determination by the IRB.

	1. Specify if your **Column C** device(s) qualifies as **Non-Significant Risk (NSR)** or **Significant Risk (SR)\*** (see Instructions).
	2. Provide information about the device’s safety and potential risks, in relation to the study’s proposed use. The IRB will make the final NSR/SR determination, but if you have evidence of a prior determination (from a sponsor or the FDA), provide an explanation. Review FDA’s full guidance on [Significant Risk and Nonsignificant Risk Medical Device Studies](https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf) to make this determination.

**\***Note: Significant Risk (SR) devices require submission of an IDE application to FDA to obtain the agency’s approval of the study. If you have an SR device, include the current status of the IDE application. You may submit an IRB protocol while the IDE is pending, but final IRB approval of your protocol will not be granted until the IDE has FDA approval. Review FDA’s guidance on the [IDE Approval Process](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm).

1. Describe your procedures for ***Column C*** device accountability: 1) how/where you will obtain the device; 2) storage/secure access; 3) dispensing to subjects; 4) tracking use and inventory; 5) disposal of device at the conclusion of the study. If you have written SOPs for these procedures, you may upload them separately to provide these details.

1. Describe your [monitoring plan](https://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf) for ensuring protocol(s) are appropriately followed during the conduct of research. Describe your plan for monitoring data and subject safety. If you have written SOPs for these procedures, you may upload them separately to provide these details.

**\*\*See Additional Regulatory Obligations for NSR/SR Devices in the Instructions portion of this Form.\*\***

**Instructions for Completion of Form 4: Devices in Human Subject Research**

1. Review FDA’s definition of [Medical Device](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm), and determine if any devices involved in this study meet the criteria:

***Medical Device:*** *An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

* *intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions
 (Examples: EEG, ECG, MRI, NIRS, TENS, Ultrasound, microneurography electrodes, low-level laser, pneumobelt, hearing aid, X-ray)* ***or***
* *intended to affect the structure or any function of the body.
(Examples: pacemakers, implants, brain stimulation devices, prosthetics)*

Any devices used in this study, even those which do not meet the definition above, must be described in the protocol - including how they operate and how they will be utilized with subjects.

1. Complete the table for each item meeting the definition of Medical Device.
	1. **Column a**: Provide the common or proprietary name of the device.
	2. **Column b**: List the manufacturer. If you are building or developing the device yourself, indicate that in this column.
	3. **Column c**: Indicate if you are testing “safety or effectiveness” of a device. This will determine applicability of FDA regulations.

***Testing Safety****: A scientific evaluation to determine if the device’s probable benefits to health outweigh any probable risks, from use of the device for its intended uses and conditions of use and when accompanied by adequate directions and warnings against unsafe use. Studies evaluating the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.* [*21 CFR 860.7(d)(1)*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D)

***Testing Effectiveness:*** *A scientific evaluation to determine whether a device is effective in providing clinically significant results in a significant portion of the target population, from use of the device for its intended uses and conditions of use and when accompanied by adequate directions for use and warnings against unsafe use.* [*21 CFR 860.7(e)(1)*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E)

***Guidance for this Determination:*** *Are you studying outcomes related to improvement of a condition in a clinical/target population (this would qualify as testing effectiveness)? Or, is the device simply a tool for measurements or eliciting physiological response, but it is not the focus of the study to determine its effectiveness (this would not qualify as testing effectiveness)? Examples:*

* *Studying whether a change or effect occurs (but not measuring improvement) from use of the device, and the subjects are healthy individuals (not a clinical/target population for the device). This would not qualify under the criteria of “testing effectiveness.”*
* *Utilizing an EEG cap as a tool to measure brain response to emotional stimuli, where the EEG is not being analyzed for its effectiveness in taking the measurements. This would not qualify under the criteria of “testing effectiveness.”*
* *Comparing “doses” of laser brain stimulation to determine which dose is most effective. This would qualify as “testing effectiveness.”*
* *Studying the improvement of PTSD symptoms after laser brain stimulation. This would qualify as “testing effectiveness.”*
* *Studying the improvement of back pain after use of the TENS device. This would qualify as “testing effectiveness.”*
* *Validating a new device through testing with human subjects to see if it works the same as a commonly used or marketed device. This would qualify as “testing effectiveness.”*
* *Testing an FDA-approved or cleared device for the purpose of evaluating a potential new use or purpose (deviation from current labeling/manual instructions). This would qualify as “testing effectiveness.”*

**Any device with a “yes” in column c will hereafter be referred to as a Column C device.**

* 1. **Column d**: Indicate the current FDA status of the device from the following options:

1) [PMA Approved](https://www.fda.gov/medical-devices/device-approvals-and-clearances/pma-approvals),
2) [510(k) Cleared](https://www.fda.gov/medical-devices/device-approvals-and-clearances/510k-clearances),
3) [510(k) Exempt,](https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions)
4) Investigational/Not Approved, or
5) Unknown.

Search for FDA status: [Registration and Listing](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053199.htm), [Databases for Approvals and Clearances](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm), [510(k) Exemptions](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm)

* 1. **Column e**: Upload the device manual and/or instructions. Upload any other relevant information about the device such as safety information, pictures, spec sheets, FDA evaluations, research publications pertaining to the device, etc.
1. Determine if your **Column C** device meets criteria as a General Wellness Device - Low Risk, Non-Medical Exercise Equipment, or IDE Exempt:

	1. **General Wellness Device – Low Risk** is a device with an intended use that (1) relates to maintaining or encouraging a general state of health or a healthy activity, or (2) relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

	To qualify as a Low Risk General Wellness Device, the device cannot be 1) invasive, 2) implanted, 3) pose a risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure. Devices determined to be General Wellness Devices are not regulated by the FDA as Medical Devices.

	Review the full FDA guidance for [General Wellness Devices](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf) to make this determination. If the device qualifies, describe specifically how your device(s) fulfills FDA’s criteria.
	2. **Non-Medical Exercise Equipment** is a device that will be utilized or tested for impact on general physical conditioning and/or for the development of athletic abilities in individuals who lack physical impairment. Exercise Equipment that is not used/studied for a “medical purpose” is not regulated by the FDA. The device will not qualify as Non-Medical Exercise Equipment if it will be used for a medical or therapeutic purpose; for example, to redevelop muscles or restore motion to joints, or for use as an adjunct treatment for obesity.
	3. **IDE Exempt:** Evaluate whether your Column C device(s) meet FDA’s criteria for [IDE Exemption by FDA](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812#812.2) below. If yes, provide an explanation of how/which criteria your device(s) meet.

*(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.*

*(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under* [*subpart E of part 807*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E?toc=1) *in determining substantial equivalence.*

*(3) A diagnostic device, if the sponsor complies with applicable requirements in* [*809.10(c)*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-809?toc=1) *and if the testing:*

*(i) Is noninvasive,*

*(ii) Does not require an invasive sampling procedure that presents significant risk,*

*(iii) Does not by design or intention introduce energy into a subject, and*

*(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.*

*(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.*

*(5) A device intended solely for veterinary use.*

*(6) A device shipped solely for research on or with laboratory animals and labeled in accordance with* [*812.5(c)*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-A/section-812.5)*.*

*(7) A custom device as defined in* [*812.3(b)*](https://www.ecfr.gov/current/title-21/section-812.3)*, unless the device is being used to determine safety or effectiveness for commercial distribution.*

 **If all Column C devices qualify under item 3 a, b, or c above, STOP HERE – you do not need to complete the remainder of the form.**

1. If your **Column C** device cannot be excluded from FDA regulations by determination as a General Wellness Device – Low Risk, Non-Medical Exercise Equipment, or IDE Exempt, the device(s) is considered a “Regulated Medical Device” and must undergo a risk determination by the IRB. Determine whether your ***Column C*** device is considered [Significant Risk (SR) or Non-Significant Risk (NSR)](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf):

	1. [***SR Device***](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)***:*** *an investigational device that:*
* *Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;*
* *Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;*
* *Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or*
* *Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.*
* *SR devices require an* [*IDE from the FDA*](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#sig_risk)*.*
	1. [***NSR Device***](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)***:*** *does not meet the definition of an SR device.*
1. Describe your procedures for device accountability. How/where will you obtain the device? Where will you store it, and how will you secure its access? What is your method for dispensing the devices (if applicable), and how will you track usage? How will you dispose of the device(s) at the conclusion of the study? If you have written SOPs for these procedures, you may upload them separately to provide these details. Please add a reference in #5 to your SOP attachments.
2. Explain how [monitoring](https://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf) the conduct of the clinical investigation and reviewing and evaluating safety information will be performed, and by whom. If you have written SOPs for these procedures, you may upload them separately to provide these details. If you have written SOPs for these procedures, you may upload them separately to provide these details. Please add a reference in #6 to your SOP attachments.

 **\*\*Additional Regulatory Obligations\*\***

**All Regulated Medical Devices**

* Studies involving Regulated Medical Devices must notify subjects in the informed consent document of the possibility that the Food and Drug Administration may inspect the records (add to Confidentiality section of informed consent).
* In accordance with FDA requirements, studies involving Regulated Medical Devices must implement the principles of Good Clinical Practice (GCP) and complete training.
	+ ICH E6(R2), “Guideline for Good Clinical Practice”: <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>
	+ GCP Training: <https://resources.uta.edu/research/regulatory-services/human-subjects/good-clinical-practices/gcp-training.php>
	+ GCP Resources/Tools: <https://resources.uta.edu/research/regulatory-services/human-subjects/good-clinical-practices/gcp-toolkit.php>
* In Investigator-initiated studies with Regulated Medical Devices, the PI is responsible for fulfilling both the Investigator and Sponsor requirements for recordkeeping and reporting as required by [FDA 812.140](https://www.ecfr.gov/current/title-21/section-812.140). In Sponsor-initiated studies, the PI is responsible for fulfilling the Investigator requirements under the same part.
* The PI is responsible for reporting any Unanticipated Adverse Device Effects to the IRB as soon as possible, but **no later than 10 days** after learning of the effect.

**Regulated Medical Devices – NSR Devices**

* NSR devices must comply with abbreviated FDA regulatory requirements under [812.2(b)(1)(i. – vii.)](https://www.ecfr.gov/current/title-21/section-812.2) and informed consent requirements under [21 CFR 50](https://www.ecfr.gov/current/title-21/part-50); however no approval by the FDA is required to proceed. The NSR determination must be confirmed by the IRB at a Full Board meeting.

**Regulated Medical Devices – SR Devices**

* SR devices must comply with FDA regulatory requirements under [812.20](https://www.ecfr.gov/current/title-21/section-812.20) and informed consent requirements under [21 CFR 50](https://www.ecfr.gov/current/title-21/part-50), including applying for FDA approval of an [IDE](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm) before initiating the study. The SR determination must be confirmed by the IRB at a Full Board meeting and confirmation of an approved IDE will be required prior to IRB approval.